DEATHS "ATTRIBUTED" TO SMOKING:

EXECUTIVE SUMMARY

Numbers of excess deaths allegedly caused by cigarette smoking are based solely on statistical associations and tell nothing about whether an individual smoker's lung cancer is "due to" smoking or some other factor or even whether particular smokers in a group of lung cancer patients "develop" the disease because of smoking.

-- Calculations of excess deaths "due to" smoking have been subject to scientific criticism over the years throughout the world. Such numbers have been referred to as "fanciful extrapolations"[1] and as belonging "to the realm of fantasy."[2]

-- The data from which such numbers are calculated suffer from biases and variations inherent in any statistical data. Even the 1989 U.S. Surgeon General's Report has acknowledged the "uncertainties" in calculating attributable risks.[3]

-- An attributable risk percentage for smoking does not and cannot take into account any agent or factor other than smoking for the disease in question.

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-- The results of intervention studies raise serious challenges regarding any claim of excess deaths from heart disease "due to" smoking.

REFERENCES

1. Rosenblatt, M.B., Statement, Re: Cigarette Labeling and Advertising - 1969." In: Hearings before the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Ninety-First Congress, First Session, 1255-1271 (at 1256), April 15-18, 21-25, 28-30, and May 1, 1969.

2. Burch, P.R.J., "Can Epidemiology Become a Rigorous Science? How Big is the Big Kill?," IRCS Journal of Medical Sciences 14: 956-961 (at 960), October, 1986.

3. U.S. Department of Health and Human Services, Public Health Service, Office on Smoking and Health, "Changes in Smoking-Attributable Mortality." In: Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General: 1989. Washington, D.C., U.S. Government Printing Office, DHHS Publication No. (CDC) 89-8411, Chapter 3, 117-169 (at 127), 1989.

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The theory that a certain number of cases of disease or deaths in a given population can be attributed to any one agent or factor has appeared in statistical journals for years. Attributed deaths are also referred to as excess deaths caused by a factor. The methods used to calculate these numbers are based on the epidemiological concept of attributable risk, often expressed as a percentage. For example, it might be said that 30 percent of cancer deaths in a group of workers are attributable to asbestos exposure.

These calculations of numbers of disease cases or deaths have nothing to do with laboratory research or the biological mechanisms underlying the disease processes. These numbers are based solely on statistical associations obtained from epidemiological studies. Consequently, when a number of excess deaths is calculated, for example, deaths from lung cancer "attributed to" smoking, this number tells nothing about whether an individual smoker's lung cancer "is due" to smoking or some other factor, nor does it even identify which smokers in a group of lung cancer patients "developed" the disease because of smoking.

Underlying the calculation of excess deaths "due to" smoking is the scientifically unjustified interpretation of the reported statistical association between smoking and disease as a causal relationship. A comment in a book titled Statistical Methods

In Cancer Research provides a cautionary note in regard to the interpretation of excess deaths and attributable risks[1]:

> Unfortunately, the only way to be absolutely certain that a causal relationship exists is to intervene actively in the system by removing the disputed factor. In the absence of such evidence, a more cautious interpretation of the attributable risk measures would be in terms of the proportion of risk explained by the given factor, where 'explain' is used in the limited sense of statistical association.

In the context of smoking, this observation is pertinent because the claimed causal relationship between cigarette smoking and certain diseases has not been scientifically established.

The calculations of excess deaths "due to" smoking have been subject to criticism over the years throughout the world. The Report of the Advisory Committee to the Surgeon General on Smoking and Health (the Terry Report) published in 1964 did not provide a calculation of a number of excess deaths "causally" related to smoking in the population because, as the Report noted, it "cannot be accurately estimated."[2] In fact, the Committee, in preparing the report, considered performing such calculations but, according to a doctor who attended their deliberations, decided against doing so because "it involves making so many assumptions that the Committee felt it should not attempt this, . . ."[3] Subsequent reports, however, have made these calculations.

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In 1969, a distinguished physician testifying before a U.S. congressional committee said "the widely publicized accusations of hundreds of thousands of deaths caused by cigarettes, and of shortening of life expectancy a specific number of minutes per cigarette smoked are fanciful extrapolations and not factual data."[4]

In 1986, a critical essay published in the IRCS Journal of Medical Sciences addressed the claim by the U.K. Health Education Council and the British Medical Association that 77,774 deaths in England and Wales were caused annually by smoking. These were deaths from heart disease, lung cancer, emphysema and bronchitis among both men and women. After a careful scientific analysis of the assumptions underlining the calculation, the researcher who authored the essay concluded that "the notorious 77 774 deaths per year have to be consigned to the realm of fantasy . . ."[5]

In 1988, a New Zealand statistician criticized the use of the attributable risk calculations in that country in a letter published in the New Zealand Medical Journal. He described estimates of death per year "due to" smoking as of "spurious accuracy" because they are based on disease rates subject to error and the assumption that statistical association is equivalent to causation.[6]

An examination of the epidemiological concepts used in calculating numbers of excess deaths will highlight specifically the uncertainties mentioned above. The attributable risk percentage for smoking is calculated by using two numbers -- the smokers' relative risk for a disease and the percentage of smokers in the population. Both of these components contribute to the uncertainty in the attributable risk percentage.

The relative risks are obtained from an epidemiological study from information on smokers' death rates and nonsmokers' death rates. Consequently, all the biases and variations in those calculations are transferred to the attributable risk calculation. In particular, if the population in an epidemiological study is not representative of the general population, the relative risks obtained from the non-representative group can be challenged when used to calculate attributable risk for the population in general. A 1987 statistical methods text, which noted that "it is difficult to obtain estimates of attributable risk," pointed out that "even cohorts such as the British doctors or US veterans differ sufficiently from the general population, in terms of economic level for example, to make extrapolation in terms of attributable risk hazardous."[7] Furthermore, the measurement of the prevalence of smoking in the population is frequently difficult to estimate accurately.

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Even the 1989 U.S. Surgeon General's Report, which makes extensive attributable risk calculations, acknowledged the "uncertainties" in attributable risks. Among the "uncertainties" listed and discussed in the report are the following: potential errors in estimating current or past cigarette use or non-use and in classifying exposure levels (e.g., amount smoked, length of time quit), the lack of representativeness of the populations studied, the failure to take into account confounding variables (e.g., occupational exposures), and errors in the classification of causes of death.[8] These sources of uncertainty, however, did not prevent the Report from calculating the well-publicized claims of 390,000 excess deaths attributable to smoking in the United States for the year 1985.

One disquieting problem with the attributable risk calculation for smoking arises when another attributable risk calculation is made for the same group for another factor or agent (e.g., occupational, diet). The two attributable risk percentages can add up to over 100 percent; this obviously leads to severe interpretational problems. For example, a report that 60 percent of the deaths in a given group are "due to" smoking and that 70 percent of the same deaths are "due to" an occupational exposure presents obvious problems. This occurs because an attributable risk percentage for smoking does not and cannot take into account any agent or factor other than smoking for the disease in ques-

tion. An epidemiologist pointed this out in discussing attributable risk as a fraction instead of a percent: "For any given individual, however, this estimate is fraught with difficulties. For one, the attributable fraction can have no unique value; when there is overlap and interaction with other factors, the estimate can always be eroded."[9]

When the attributable risk formula was examined from a statistical perspective in view of its possible adoption by the U.S. Congress as a method of compensation in radiation and cancer cases, a statistician concluded that ". . . it is inappropriate either as a statistical measure of probability of causation or as a guide to share in causation."[10]

A review of lists of causes of death attributed to smoking reveals that a large number of those deaths occur as a result of heart disease. An examination of recent epidemiological results demonstrates how unreasonable this attribution is. An alternative way of looking at attributable risk is to look at it as a measure of the decrease in a disease if the population was no longer exposed. Simply stated, according to the causal theory, if no one smoked, a number of heart disease deaths would be avoided.

This question was addressed by an expensive and lengthy epidemiological study conducted in the United States which made

use of randomization in its design. The use of randomization represents the closest approach to rigorous scientific conditions possible in an epidemiological study. The investigators randomly assigned a population of men at high risk for heart disease to two groups, one of which (called the Intervention Group) was intensively counseled to quit smoking, to lower their blood pressures, and to reduce their blood cholesterol levels. After follow-up, during which significant smoking reduction occurred in the Intervention Group, the death rates from heart disease were found to be approximately the same in both groups, a result which the investigators did not expect.[11] Hence, any claim of excess deaths from heart disease "due to" smoking, in light of this study, can be seriously challenged.

Recently, some countries have been attributing deaths to smoking apparently using information from epidemiological studies conducted in other countries. This type of calculation is subject not only to the criticisms discussed above but to the additional scientific question of whether foreign study populations are relevant to a native population. If the British doctors are not representative of the British population and the American Cancer Society population is not representative of the U.S. population, it is scientifically inappropriate to base calculations of excess deaths in yet a third country on those studies.[12]

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In conclusion, the calculations of excess deaths "due to" smoking may have appeal for government officials and health societies, but the scientific weaknesses and uncertainties inherent in these numbers make their wide publicity inadvisable and misleading.

REFERENCES

1. Breslow, N.E. and Day, N.E., "Fundamental Measures of Disease Occurrence and Association." In: Statistical Methods in Cancer Research. Volume 1 - The Analysis of Case-Control Studies. Lyon, France, International Agency for Research on Cancer, IARC Scientific Publications No. 32, Chapter 11, 42-81 (at 78), 1980.

2. U.S. Department of Health, Education, and Welfare, "Summaries and Conclusions." In: Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service. Public Health Service Publication No. 1103, Washington, D.C., U.S. Government Printing Office, Chapter 4, 23-40 (at 31), 1964.

3. Hundley, J.M., Transcript of news conference released by U.S. Public Health Service, January 11, 1964.

4. Rosenblatt, M.B., Statement, Re: Cigarette Labeling and Advertising - 1969." In: Hearings before the Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Ninety-First Congress, First Session, 1255-1271 (at 1256), April 15-18, 21-25, 28-30, and May 1, 1969.

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5. Burch, P.R.J., "Can Epidemiology Become a Rigorous Science? How Big is the Big Kill?," IRCS Journal of Medical Sciences 14: 956-961 (at 960), October, 1986.

6. Mullins, P.R., "The Cost of Cigarette Smoking," New Zealand Medical Journal 101(850): 491, July 27, 1988.

7. Breslow, N.E. and Day, N.E., "The Role of Cohort Studies in Cancer Epidemiology." In: Statistical Methods in Cancer Research. Volume II - The Design and Analysis of Cohort Studies. Lyon, France, International Agency for Research on Cancer, IARC Scientific Publications No. 82, Chapter 1, 1-46 (at 21), 1987.

8. U.S. Department of Health and Human Services, Public Health Service, Office on Smoking and Health, "Changes in Smoking-Attributable Mortality." In: Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General: 1989. Washington, D.C., U.S. Government Printing Office, DHHS Publication No. (CDC) 89-8411, Chapter 3, 117-169, 1989.

9. Susser, M., "Rules of Inference in Epidemiology," Regulatory Toxicology and Pharmacology 6: 116-128 (at 119), June, 1986.

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10. Cox, L.A., Jr., "Statistical Issues in the Estimation of Assigned Shares for Carcinogenesis Liability," Risk Analysis 7(1): 71-80 (at 72), 1987.

11. Multiple Risk Factor Intervention Trial Research Group, "Multiple Risk Factor Intervention Trial: Risk Factor Changes and Mortality Results," Journal of American Medical Association 248(12): 1465-1477, September 24, 1982.

Multiple Risk Factor Intervention Trial Research Group, "Mortality Rates After 10.5 Years for Participants in the Multiple Risk Factor Intervention Trial: Findings Related to a Priori Hypotheses of the Trial," Journal of American Medical Association 263(13): 1795-1801, April 4, 1990.

12. Rutsch, M., "Mortalität, Rauchen und Statistik (Mortality, Smoking and Statistics)," Statistische Hefte: Internationale Zeitschrift für Theorie und Praxis 20(3): 160-171, 1979. Translation.